IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO ETHICON WAVE 12 CASES LISTED IN EXHIBIT A	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MOTION TO EXCLUDE CERTAIN GENERAL OPINIONS OF NIALL GALLOWAY, M.D., FOR WAVE 12

Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon") hereby move to exclude certain general opinions offered by Dr. Niall Galloway.

Specifically, the Court should exclude (1) Dr. Galloway's opinions about mesh degradation, which he is not qualified to provide, (2) opinions about a "public health crisis," "new disease," or new field of "meshology" as a result of pelvic mesh complications, which are irrelevant and unfairly prejudicial, and (3) legal conclusions and terminology, which are improper.

BACKGROUND

Dr. Galloway is a urologic surgeon. He has been designated as a general and case-specific expert in two Wave 12 cases. He offers a combined general and case-specific report for each of these cases, attached as Exhibits 1 and 2 (*Carbon* and *Acosta* reports). The general portions of these reports are almost identical.

Dr. Galloway's CV does not demonstrate any training or expertise in product design or manufacturing. *See* Galloway *Carbon* Report, Ex. 1. Dr. Galloway has testified that he does not

hold himself out as a biomaterials or bioengineering expert. Ex. 3, Galloway 6/09/16 1:49 p.m. Dep. Tr. 96:17-22. He also has no experience in mesh manufacturing. *Id*. at 96:23-97:1.

ARGUMENT

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. Rule 702 requires that the district court "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579, 589 (1993). "To be relevant under *Daubert*, the proposed expert testimony must have 'a valid scientific connection to the pertinent inquiry as a precondition to admissibility.'" *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (citing *Daubert*, 509 U.S. at 592). To be reliable, the opinion must be "based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Id.* (quoting *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999)). The expert must be qualified to offer the opinion "by knowledge, skill, experience, training, or education. " Fed. R. Evid. 702. The proponent of the expert testimony must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm–O–Disc, Inc.*, 137 F.3d 780, 783 (4th Cir.1998).

Applying those standards here, certain of Dr. Galloway's opinions should be excluded.

I. The Court should preclude Dr. Galloway from testifying about alleged mesh degradation.

In his Reports, Dr. Galloway opines that mesh degrades and that "placing a material that degrades, releases potentially toxic chemicals, and creates a chronic inflammatory response, is a

flaw in the design of Ethicon's vaginal mesh devices." Ex. 1, Report at 4-6. As support for his opinion, Dr. Galloway does not cite any personal experience or observation. Rather, he cites scientific literature which he claims "confirmed degradation in explanted vaginal mesh." *Id.* at 6. Dr. Galloway is not qualified to offer this opinion. *See* Fed. R. Evid. 702.

As his curriculum vitae plainly discloses, and as he himself admitted in his deposition, Dr. Galloway is *not* a biomaterials expert. *See* Exhibit 1, Curriculum Vitae; Ex. 3, Galloway 6/09/16 1:49 p.m. Dep. Tr. 96:17-22. Nor is he a pathologist. He does not have a demonstrated background in polymer chemistry or biochemical or biomechanical engineering, and his disclosed background indicates that he has never performed any bench research with respect to polypropylene. *See id.* Nothing else in Dr. Galloway's experience as a urologic surgeon would inform his opinion that mesh, a biomaterial, degrades in the human body.

In other mesh litigation, the proffered experts' qualifications to opine about biomaterial properties such as degradation and porosity have been closely scrutinized and such testimony has been limited to experts with extensive biomaterial and biomechanical engineering education and experience. *See In re C.R. Bard, Inc., Pelvic Repair Sys. Liab. Litig.*, 948 F. Supp. 2d 589, 623 (S.D. W. Va. 2013) (allowing physician testimony regarding biomechanical analysis of mesh only after establishing that physician had two engineering degrees, had practiced as an engineer for twelve years, and had focused on studying biomechanical analysis of pelvic floor structures and the pelvic floor from an engineering perspective for ten years); *id.* at 633 (expressing "concerns about [physician's] qualifications to testify specifically as to the properties of polypropylene" mesh, but allowing testimony only after establishing that physician not only had a biomedical engineering degree, but also routinely evaluated biomaterials, developed new biomaterials and modified existing biomaterials, and had specific experience with polymeric material). Dr. Galloway has no such experience here.

Although the Court has permitted expert physicians to offer opinions about "mesh reaction to and effect on the human body," Dr. Galloway's opinions about degradation go beyond that. *In re: Ethicon, Inc.*, 2:12-MD-02327, 2016 WL 4536885, at *3 (S.D.W. Va. Aug. 30, 2016). Dr. Galloway is not simply opining about mesh reactions he has observed in his practice. Rather, he is opining about the *mechanism* for the reaction, one that he cannot readily observe. As Dr. Galloway admits, degradation can only be determined through a pathological examination:

> Q. To the extent, if we assume that degradation can occur in vivo, the only way to determine whether mesh is actually degraded is through a pathological examination of the explanted mesh, correct?
> A. Yes, that's correct.

Ex. 4, Galloway 3/4/16 Tr. at 99:24-100:6 (objection omitted).

Dr. Galloway has not performed any such pathological analyses, nor would he have the expertise to do so. Dr. Galloway's opinions about degradation should be excluded.

II. Dr. Galloway's opinions about a "public health crisis," "new disease," or new field of "meshology" as a result of pelvic mesh complications should be excluded.

In his Reports, Dr. Galloway offers certain opinions about the ramifications of pelvic mesh complications, opining: (1) that "a public health crisis has been created," (2) that he is "not aware of any other surgical procedure that has created a 'new disease' such as that we are seeing since the introduction of trans-vaginal mesh," and (3) that "[i]t has even been given a name in the recent literature, 'Meshology.'" Ex. 1, Report at 2, 17. These opinions are entirely irrelevant and unfairly prejudicial.

Here, the jury will be tasked to determine whether the warnings of the devices were adequate and whether they are defective. Dr. Galloway's opinions about the impact of mesh-related complications on the medical field do absolutely nothing to assist the jury with answering those questions. Rather, they are inflammatory characterizations calculated to provoke sympathy

and anger from the jury. *See* Fed. R. Evid. 403; *Hogan v. Novartis Pharms. Corp.*, 2011 U.S. Dist. LEXIS 43800 (E.D.N.Y. Apr. 23, 2011) (excluding testimony where "plaintiff is attempting to use an expert witness to make her closing argument rather than relate scientific conclusions"); *In re Air Crash Disaster at New Orleans, La.*, 795 F.2d 1230, 1233 (5th Cir. 1986) (noting that "the trial judge ought to insist that a proffered expert bring to the jury more than the lawyers can offer in argument"). Accordingly, these opinions should be exclude Fed. R. Civ. Proc. 403 and 401.

III. The Court should exclude improper legal conclusions offered by Dr. Galloway.

Dr. Galloway's Reports include a number of improper legal conclusions which invade the province of the judge and jury. Specifically, Dr. Galloway opines that the devices were "unreasonably dangerous," Ex. 1, Report at 25; that there were "defects in armed transvaginal mesh," *id.* at 7; and that "a product may be defective if the risks do not outweigh the benefits or is 'not reasonably safe,'" *id.* at 13. He also opines at various points that the devices are "flawed," a term highly suggestive of "defective." *E.g.* Ex. 1, Report at 4, 5, 6, 8, 10, 11.

This Court has repeatedly held that experts may not provide opinion testimony that states a legal standard, uses a legal term of art, or draws a legal conclusion by applying law to the facts—e.g., "failed to adequately disclose," "failed to warn on its label," "defective," "unreasonably dangerous," "not reasonably safe," "reasonable and prudent medical device manufacturer." *See, e.g., In re: Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4536885, at *4 (S.D.W. Va. Aug. 30, 2016); *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 629 (S.D.W. Va. 2013); *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *3 (S.D.W. Va. Apr. 24, 2015); *Lewis v. Ethicon, Inc.*, No. 2:12-CV-4301, 2014 WL 186872, at *21 (S.D.W. Va. Jan. 15, 2014); *see also United States v. McIver*, 470 F.3d

550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible.").

Accordingly, Dr. Galloway's use of legal terminology and legal conclusions should be prohibited.

CONCLUSION

For these reasons, the following opinions should be excluded: (1) Dr. Galloway's opinions about degradation and any other biomaterials issues, (2) opinions about a "public health crisis," "new disease," or new field of "meshology" as a result of pelvic mesh complications, and (3) improper legal conclusions.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this day I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage